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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,216	06/29/2005	Mark Tawa	TP15013USPTC6	4554

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1627

NOTIFICATION DATE	DELIVERY MODE
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12/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/541,216	Applicant(s) TAWA ET AL.	
	Examiner Renee Claytor	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicants argue over the 35 USC 102 rejection over Remenar and point out that Remenar claims priority to 60/456,027 and 60/437,516, which the present application also claims priority to. Applicants assert that because these two applications share priority that the rejection should be withdrawn.

In response to the above arguments, it is noted that Remenar (US PgPub 2006/0052432) claims priority to Provisional applications that the present application do not claim priority to. In particular, Remenar claims priority to 60/427,086 which was filed on 11/15/2002 and gives priority to the Remenar application. In particular, the priority document teaches a salt for of an API and in particular, celecoxib. A precipitation retardant is also taught that can be a poloxamer (pages 10, 17, 20 of 60/427,086). Therefore, priority for the teachings of Remenar goes to at least 11/15/2002 and the rejection is deemed proper and is maintained.

Applicants argue over the 35 USC 103 rejection over Tawa et al. (US PgPub 2007/0015841) in view of Remenar et al. (US PgPub 2006/0052432). Applicants argue that Tawa et al. is now patented and claims priority to six provisional patent applications and the present application claims priority to each of these applications and Tawa et al. cannot be prior art.

In response to the above arguments, it is noted that the document that was used in the rejection was not the now patent but the PgPub 2007/0015841 which claims priority to many different provisional applications that claim priority to dates before the

priority date of the present invention. Therefore, Applicants arguments are not found persuasive and the rejection is maintained.

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46-68 rejected under 35 U.S.C. 102(e) as being anticipated by Remenar et al. (US PgPub 2006/0052432)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Remenar et al. teaches pharmaceutical compositions that include an API having low aqueous solubility that is less than or equal to 10 mg/mL (paragraph 0172). It is taught that the API is formulated with a precipitation retardant (paragraph 0174). The precipitation retardants, such as poloxamers, have an interfacial tension less than 10

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dyne/cm and a surface tension less than 42 dyne/cm (paragraph 0174). Also included in the compositions are precipitation retardant enhancers which include hydroxypropyl cellulose (paragraph 0182). In preferred embodiments, the compositions comprise a salt of celecoxib that is an alkali metal salt including sodium, potassium and lithium (paragraphs 0199 and 0200). Example 15 teaches a formulation with celecoxib sodium salt hydrate and a poloxamer and hydroxypropyl cellulose (if added). The compositions are formulated for oral administration (paragraph 0076).

The claim limitations in claims 52-54 that recite crystallization or precipitation is retarded for a specific amount of time is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claims limitations in claims 60-62, 66-68 that recite the bioavailability of the composition is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claim limitations in claims 63-65 that recited the Cmax of the composition is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-68 rejected under 35 U.S.C. 103(a) as being unpatentable over Tawa et al. (US PgPub 2007/0015841) in view of Remenar (US PgPub 2006/0052432).

Tawa et al. teach a salt form of celecoxib that is significantly more stable in water than neutral celecoxib, in addition to a binding agent that includes poloxamers (attention is drawn to Poloxamer 188 and Poloxamer 237; paragraphs 0116-0117, 130). The salt forms of celecoxib include metal salts such as sodium salt (paragraph 0068). The compositions are formulated as oral formulations (paragraph 0068). The compositions optionally comprise a binding agent such as hydroxypropylcellulose (paragraph 0115).

Tawa et al. does not teach that the surfactant exhibits an interfacial tension of less than about 10 dyne/cm or a surface tension of less than about 42 dyne/cm.

Remenar teaches that Poloxamer 188 and Poloxamer 237 are poloxamers that have a surface tension of less than 42 dyne/cm and an interfacial tension of less than 10 dyne/cm.

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Tawa et al. which teaches compositions comprised of a salt form of celecoxib mixed with a poloxamer, with the teachings of Remenar which teaches that Poloxamer 188 and Poloxamer 237 (which are used in the

invention of Tawa). One would be motivated to use the teachings of Remenar to verify the interfacial tension and surface tension of the poloxamer which will help solubilize the celecoxib salt.

The claim limitations in claims 52-54 that recite crystallization or precipitation is retarded for a specific amount of time is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claims limitations in claims 60-62, 66-68 that recite the bioavailability of the composition is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claim limitations in claims 63-65 that recited the Cmax of the composition is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627